

### ***DETAILED ACTION***

#### **I. Action Summary**

The finality of the action sent on December 1, 2008 is hereby withdrawn. After the Examiner's amendment below claims 15 and 20 are in condition for allowance.

#### **II. Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a phone conversation with MaryAnne Armstrong on November 23, 2009.

The application has been amended as follows:

Please, **CANCEL** claims 13, 14, 16-19 and 21-23.

In claim 15, line 1, please **DELETE** [of claim 13, being].

In claim 20, line 2, please **REPLACE** [a salt of claim 13] with ---the salt of claim 15--.

#### **III. Substance of the Interview**

After discussions with Mr. James Wilson, he instructed Examiner Rodriguez-Garcia with Primary Examiner Laura Stockton to call Applicant's representative, Ms. MaryAnne Armstrong, on 11/19/2009 to inform them of possible allowance. Applicants were informed that the signed Declaration showing unexpected results received on November 10, 2008 would overcome the obviousness rejection to claim 15.

Claim 15 would be allowable if rewritten in independent form.

On November 23, 2009, Ms. Armstrong instructed the Examiner to CANCEL the non-elected subject matter and amend claim 15 to make it independent.

#### **IV. Reasons for Allowance**

The following is an examiner's statement of reasons for allowance:

Claims 13-15 and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Scheel-Kruger *et al.* (US 6,288,079B1) as evidenced by Berge *et al.* (J. Pharm. Sci. 1977; 66(1);1-19). Scheel-Kruger *et al.* (US Patent 6,288,079 B1) is the closest prior art to Applicant's invention, disclosing a citrate salt of the same tropane compound. Applicants claim the monohydrate tartrate salt of the tropane compound. Applicants provided a signed Declaration on November 10, 2008 which shows unexpected improvement in hygroscopic properties of the claimed tartrate salt monohydrate. The claimed tartrate salt monohydrate is much less hygroscopic than the tropane citrate salt. Moreover, the reference Keverline-Frantz *et al.*, provided and discussed by Applicants in the Remarks of March 31, 2009, show that tartrate salts of several tropane compounds are hygroscopic. Therefore, it would have not been obvious to expect that the instantly claimed tropane tartrate salt monohydrate would be non-hygroscopic. Therefore, claims 15 and 20 are now allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

**V. Telephone Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624

/V. R. G./  
Examiner, Art Unit 1626